

REMARKS

Upon entry of the present amendment, claims 1, 3-11, 13-15, 17-22 and 24 will remain pending in the above-identified application, with claims 1, 3-11, 13-15, 17 and 24 standing ready for further action on the merits, and remaining claims 18-22 being withdrawn from consideration based on an earlier restriction requirement of the Examiner. Claims 1, 5-6, 10, 13-15, and 24 have been amended herein, and claims 2, 12, 16, 23 and 25 have been canceled herein.

The present amendments do not introduce new matter into the application as originally filed. For example, the amendment to claim 1 finds support in prior claims 2 and 23, which are now canceled. Similarly, support for amended claim 15 is found in prior claim 16, now canceled.

Additionally, claims 5-6, 10 and 13-14 have been amended to change their dependencies to claim 1. Claims 13-14 have additionally been grammatically amended to agree with language found in claim 1. Additionally, claim 24 has been rewritten/redrafted into an independent format by incorporating limitations from claim 18.

Accordingly, entry of the instant amendment and favorable action on the merits is earnestly solicited at present.

Rejections of Claim 25

Claim 25 has been rejected under the provisions of 35 U.S.C. § 112, second paragraph, and also 35 U.S.C. § 101. Since claim 25 has been canceled in the instant reply, withdraw of the rejections thereof is required.

Claim Rejections under 35 U.S.C. § 112

Claims 1-17 and 23-24 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is submitted that the terms “good solvent” and “poor solvent” as they are used in the instant claims are “art recognized terms” commonly used by those skilled in the art. For example, they are used in each of U.S. patents 6,531,490; 6,455,238 and 6,087,471.

U.S. Patent No. 6,531,490 (Claim 1)

1. A process for producing spherical agglomerates of inogatran comprising the consecutive steps of: a) dissolving an unstable, hygroscopic, hydrate form of inogatran in a mixture of a good solvent for inogatran and a poor solvent for inogatran to form a concentrated solution; b) optionally filtering the solution; c) concentrating the concentrated solution further by evaporation; d) adding a non-solvent for inogatran to the concentrated solution until the solution becomes supersaturated; and e) adding additional non-solvent when nucleation has started to produce a product comprising spherical agglomerates of inogatran, wherein the solubility of inogatran in the good solvent is more than about 0.03 g inogatran/g solvent, the solubility of inogatran in the poor solvent is about 0.0001-0.03 g inogatran/g solvent, and the solubility of inogatran in the non-solvent is less than about 0.0001 g inogatran/g solvent. (emphasis added)

U.S. Patent No. 6,455,238 (Claim 1)

1. A method of main a photographic imaging element having a protective overcoat thereon, comprising the following steps: (a) forming a coating composition comprising a water insoluble polymer dissolved homogeneously in a solvent mixture, said solvent mixture comprising at least one solvent which is a relatively good solvent for said water-insoluble polymer and at least one solvent which is a relatively poor solvent for said water-insoluble polymer, said relatively poor solvent having a higher boiling point than said relatively good solvent, (b) applying the coating composition to a substrate comprising at least one silver-halide light-sensitive emulsion layer and a support; (c) drying the coated substrate to remove substantially all of the solvents to obtain a photographic element having a open-pore membrane, whereby the minimum porosity of the open-pore membrane is 20 percent. (emphasis added)

U.S. Patent No. 6,087,471 (Claim 1)

*1. A method for recovering PHA from biomass comprising:
providing biomass containing a PHA;
dissolving the PHA with an effective PHA-poor solvent to produce PHA-enriched solvent and residual biomass materials, wherein the dissolving is performed under pressure and at temperatures above the boiling point of the PHA-poor solvent;
separating the residual biomass materials from the PHA-enriched solvent;
reducing the temperature of the PHA-enriched solvent to cause PHA precipitation;
and
recovering the precipitated PHA polymer. (emphasis added)*

Additionally, it is submitted that the meaning and scope of the terms "good solvent" and "poor solvent" can be easily determined from the description of the instant application at page 7, line 18 to page 8, line 16, which is reproduced immediately below.

The "good solvent or mixture of good solvents" in the present invention is not specifically limited, as long as it can fully dissolve the drug. For example, lower alcohols such as methyl alcohol, ethyl alcohol, n-propyl alcohol or isopropyl alcohol; ketone solvents such as acetone or methyl ethyl ketone; as well as acetonitrile, dioxane, methyl ether, ethyl ether, chloroform, dichloromethane, trichloromethane; and mixtures of these solvents may be proposed.

The "poor solvent or mixture of poor solvents" in the present invention is not specifically limited, as long as it is a solvent or a mixture of good solvents not substantially dissolving the drug and is a solvent miscible with the drug-containing solution of a good solvent or a mixture of good solvents. For examples, water, acidic waters containing a variety of acids, and basic waters containing a variety of bases may be proposed.

The mixing ratio of the drug-containing solution to the poor solvent or mixture of poor solvents is not specifically limited, as long as deposition or precipitation of the drug occurs. The amount of the drug-containing good solvent or mixture of good solvents to be mixed is generally 0.001% to 50% (V/V), preferably 0.01% to 10% (V/V), and more preferably 0.01% to 5% (V/V) to the amount of the poor solvent or mixture of poor solvents.

Accordingly, it is submitted that the good solvent is a solvent in which a solute is soluble well. The poor solvent a solvent in which a solute is soluble only in a limited amount.

Reconsideration and withdraw of the outstanding rejection is thus required at present.

Claim Rejections over the Cited Art

Claims 1, 4-5, 7-11 and 15 are rejected under 35 U.S.C. § 102(b) as being anticipated by Sjostrom et al. WO '593 (WO 90/15593).

Claims 1, 3-6, 9, 11-12, 15 and 17 are rejected under 35 U.S.C. § 102(e) as being anticipated by Chaubal et al. US '662 (US 2004/0245662).

Claims 2 and 17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Chaubal et al. US '662.

Claims 13 and 14 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Sjostrom et al. WO '593 in view of Bosch et al. US '118 (US 5,510,118).

Claims 23-25 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Sjostrom et al. WO '593 in view of Feldmann US '234 (US 2,652,234).

Reconsideration and withdraw of each of the above rejections is respectfully requested based on the amendments made herein, and the following considerations.

Legal Standard for Determining Anticipation

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "When a claim covers several structures or compositions, either generically or as alternatives, the claim

is deemed anticipated if any of the structures or compositions within the scope of the claim is known in the prior art.” *Brown v. 3M*, 265 F.3d 1349, 1351, 60 USPQ2d 1375, 1376 (Fed. Cir. 2001) “The identical invention must be shown in as complete detail as is contained in the ... claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

Legal Standard for Determining Prima Facie Obviousness

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

“There are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art.” *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998) (The combination of the references taught every element of the claimed invention, however

without a motivation to combine, a rejection based on a *prima facie* case of obvious was held improper.).

“In determining the propriety of the Patent Office case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the reference before him to make the proposed substitution, combination, or other modification.” *In re Linter*, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972).

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. “The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art.” *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000). See also *In re Lee*, 277 F.3d 1338, 1342-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002) (discussing the importance of relying on objective evidence and making specific factual findings with respect to the motivation to combine references); *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

The Supreme Court of the United States has recently held that the teaching, suggestion, motivation test is a valid test for obviousness, but one which cannot be too rigidly applied. See *KSR Int’l Co. v Teleflex Inc.*, 127 SCt 1727, 82 USPQ2d 1385 (U.S. 2007). The Supreme Court

in *KSR Int'l Co. v. Teleflex, Inc.*, *ibid.*, reaffirmed the Graham factors in the determination of obviousness under 35 U.S.C. § 103(a). The four factual inquiries under Graham are:

- (a) determining the scope and contents of the prior art;
- (b) ascertaining the differences between the prior art and the claims in issue;
- (c) resolving the level of ordinary skill in the pertinent art; and
- (d) evaluating evidence of secondary consideration.

Graham v. John Deere, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (U.S. 1966).

The Court in *KSR Int'l Co. v. Teleflex, Inc.*, *supra.*, did not totally reject the use of "teaching, suggestion, or motivation" as a factor in the obviousness analysis. Rather, the Court recognized that a showing of "teaching, suggestion, or motivation" to combine the prior art to meet the claimed subject matter could provide a helpful insight in determining whether the claimed subject matter is obvious under 35 U.S.C. § 103(a).

Even so, the Court in *KSR Int'l Co. v. Teleflex, Inc.*, *ibid.*, rejected a rigid application of the "teaching, suggestion, or motivation" (TSM) test, which required a showing of some teaching, suggestion, or motivation in the prior art that would lead one of ordinary skill in the art to combine the prior art elements in the manner claimed in the application or patent before holding the claimed subject matter to be obvious.

Accordingly, while the courts have adopted a more flexible teaching, suggestion, motivation (TSM) test in connection with the obviousness standard based on the *KSR v. Teleflex* case, which case involved a mechanical device in a relatively predictable technological area, it remains true that, despite this altered standard, the courts recognize inventors face additional

barriers in relatively unpredictable technological areas as noted in *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, 83 USPQ2d 1169 (Fed. Cir. 2007).

Further, the Examiner bears the initial burden of presenting a *prima facie* case of obviousness. *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). “[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336, quoted with approval in *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (2007).

Exemplary rationales are set forth in MPEP § 2141 that may support a conclusion of obviousness, and include:

(a) combining prior art elements according to known methods to yield predictable results;

(b) simple substitution of one known element for another to obtain predictable results;

(c) use of known technique to improve similar devices (methods, or products) in the same way;

(d) applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;

(e) “obvious to try” – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success

(f) known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;

(g) some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

Additionally, MPEP § 2143.03 clearly directs that all claim limitations must be considered in view of the cited prior art in order to establish a prima facie case of obviousness.

Distinctions Over the Cited Art

Anticipation

As indicated above, instant claim 1 has been amended to recite limitations previously found in claims 2 and 23. Since neither of claims 2 or 23 was previously rejected based on an allegation of anticipation, it follows that amended claim 1, and its dependent claims 3-11 and 13-14 are incapable of being anticipated by the cited art of Sjostrom et al. WO '593 or Chaubal et al. US '662.

Additionally, since claim 15 now recites limitations previously recited in claim 16, which was never rejected for anticipation over the cited art references of Sjostrom et al. WO '593 or Chaubal et al. US '662, it follows that amended claim 15 and its dependent claim 17 are also incapable of being anticipated by the applied cited art.

Obviousness

It is submitted that the cited art being applied against instantly amended pending claims 1, 3-11, 13-15, 17 and 24 that are under consideration at present, fails to provide any teaching or reason or rationale to those of ordinary skill in the art that would allow them to arrive at the instant invention as claimed.

Likewise, it is submitted that the record of prosecution in the instant application also fails to properly set forth any reason or rationale that would allow one of ordinary skill in the art to arrive at the invention recited in any one of independent claims 1, 15 or 24, which are currently

under consideration at present, or any of the remaining claims 3-11, 13-14 and 17 that depend therefrom.

Accordingly, reconsideration and withdraw of each of the outstanding obviousness rejections over the cited art of Chaubal et al. US '662, Sjostrom et al. WO '593, Bosch et al. US '118 and Feldmann US '234 is required at present.

Any contention of the USPTO to the contrary must be reconsidered at present.

Conclusion

In view of the above amendment, applicant believes the pending application is in condition for allowance. As such, the USPTO is respectfully requested to issue a Notice of Allowance, clearly indicating that each of instant claims 1, 3-11, 13-15, 17 and 24 are allowed and patentable under the provisions of Title 35 of the United States Code.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact John W. Bailey, Reg. No. 32,881 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

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Reply to Office Action of July 28, 2008

Docket No.: 0425-1236PUS1

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

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